APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,566	02/05/2001	Jay M. Short	DIVER1370-6	4776

25225 7590 12/19/2006		EXAMINER
MORRISON & FOERSTER LLP		RAMIREZ, DELIA M
12531 HIGH BLUFF DRIVE		
SUITE 100	ART UNIT	PAPER NUMBER
SAN DIEGO, CA 92130-2040	1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

PTOL-90A (Rev. 10/06)

	Application No.	Applicant(s)
Office Action Summary	09/777,566	SHORT ET AL.
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>18 September 2006</u>.

2a)☒ This action is **FINAL.**   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-33,35,36,38-43,45,46,81-88 and 92-98* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16-33,35,36,38-43,45,46,81-88 and 92-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-SB/08)
    Paper No(s)/Mail Date <u>6/30/06,9/18/06</u>.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-13, 16-33, 35-36, 38-43, 45-46, 81-88, 92-98 are pending.

Applicant's amendment of claims 1-2, 5, 6-7, 10-12, 16, 35-36, 38-43, 45-46, 81-88, 92-

98, and cancellation of claims 89-91 in a communication filed on 9/18/2006 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby

withdrawn.

Information Disclosure Statement

1.   The information disclosure statements (IDS) submitted on 6/30/2006 and 9/18/2006 are

acknowledged. Reference 3 of the IDS filed on 6/30/2006 has not been considered as no copy of

such European Search Report has been provided. The remaining references are being considered

by the examiner.

Specification

2.   Applicant's amendment of the specification filed on 9/18/2006 correcting minor

typographical errors and deleting a hyperlink is acknowledged. In view of this amendment,

previous objections to the specification are hereby withdrawn.

Claim Objections

3.   Claim 2 is objected to due to the recitation of "nucleotide sequence ..., further

comprising a nucleotide sequence encoding a coding and/or non-coding sequence". For clarity

and consistency, it is suggested that the term be amended to recite "nucleotide sequence ...,

further comprising a coding and/or non-coding sequence". Appropriate correction is required.

4.   Claims 2, 10-12, 16, 35-36, 38-43, 45-46, 81-88, 92-94, 97-98 are objected to due to the

recitation of "nucleotide sequence of ... lacking a nucleic acid encoding.... or comprising a

nucleic acid encoding...." and similar language for the following reasons. There is lack of

consistency in these claims in view of the fact that in the same sentence, the terms "nucleotide

sequence" and nucleic acid appear to be used interchangeably even though the art recognizes that

these terms are not the same.   For example, in the phrase indicated above, a nucleotide sequence

lacks a nucleic acid. As known in the art, a nucleotide sequence is a graphical representation of

the order in which nucleotides are arranged in a nucleic acid molecule.   Thus, these terms are

not equivalent. Usage of these terms interchangeably can lead to confusion. Applicant is

requested to review and amend all these claims to ensure that there is consistency in the language

used. Appropriate correction is required.

5.   Claim 10 is objected to due to the recitation of "(vi) comprises an amino acid sequence of

(iv) or (v)". It should be amended to recite "(vi) comprises the amino acid sequence of (iv) or

(v)" since the amino acid sequence has been defined in (iv) and (v). Appropriate correction is

required.

6.   Claim 35 is objected to due to the recitation of "comprising a nucleic acid (i)...(vi) a

nucleic acid completely complementary ...." as the term "a nucleic acid" in (vi) is redundant in

view of the fact that the preamble already indicates that items (i)-(vi) are nucleic acids.

Appropriate correction is required.

7.   Claims 36, 38-43, 92-94, 97-98 are objected to due to the recitation of "the complete

complement of the nucleic acid encoding the polypeptide of (x), (y) or (z) ..." for the following

reasons. The items of (x), (y) or (z) are not polypeptides but nucleic acids. While it is understood

that the recitation of "polypeptides of (x), (y) or (z)" refers to the polypeptides encoded by the

nucleic acids of (x), (y), or (z), it is suggested that for clarity and consistency, the term be

amended to recite "the complete complement of the nucleic acids of (x), (y)......". Appropriate

correction is required.

8.   Claims 36, 38-43 are objected to due to the recitation of "comprises" in item (viii). For

consistency, the proper form of the term should be "comprising" since that is the form of the verb

used in all other items. Appropriate correction is required.

9.   Claim 46 is objected to due to the recitation of "comprising" in items (iii)-(iv). For

consistency, the proper form of the term should be "comprises" since that is the form of the verb

used in all other items. Appropriate correction is required.

10.   Claim 81 is objected to due to the recitation of "encoding" in item (iv). For consistency,

the proper form of the term should be "encodes" since that is the form of the verb used in all other

items. Appropriate correction is required.

11.   Claims 83, 85, 86, 87 are objected to due to the recitation of "comprising a nucleic acid

(1)...(2) a nucleic acid comprising a sequence that is the complete complement ...." as the term

"a nucleic acid" in (2) is redundant in view of the fact that the preamble already indicates that

items (1)-(2) are nucleic acids. Appropriate correction is required.

12.   Claims 83-88 are objected to due to the recitation of "nucleic acid comprising a sequence

that is the complete complement of..., wherein the nucleic acid is operably linked to a

transcriptional control sequence" for the following reasons. As known in the art, the complete

complement of a polynucleotide if expressed would encode a totally different protein from that

encoded by the polynucleotide. Therefore, if the limitation requiring the nucleic acid to be

operably linked to a transcriptional control sequence is applied to the complete complement, it

would appear as if the intended protein is not the phytase but a protein of unknown function

encoded by the complete complement of the polynucleotide encoding the phytase. Appropriate

correction is required.

13.   Claims 83-88 are objected to for the following reasons. While it is understood that

claims 83-88 refer to a phytase which is a variant of the polypeptide of SEQ ID NO: 2 which is

95% sequence identical, or an enzymatically active fragment of a variant of the polypeptide of

SEQ ID NO: 2 which is 95% sequence identical, the claims are written such that it is not

completely clear when first read that the phytase being recited is a variant of what is recited in (1)

prior to the description of conservative substitutions allowed. It is suggested that the claims be

amended to indicate, for example, in the preamble, that what is first recited in (1) is not

describing the actual phytase but instead is describing the phytase to which the substitutions are

made. Appropriate correction is required.

14.   Claim 94 is objected to due to the recitation of "comprising" in item (vii) and "encoding"

in item (viii). For consistency, the proper form of the terms should be "comprises" and "encodes"

since that is the form of the verbs used in all other items. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

15.   The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

16.   Claims 1-13, 16-33, 35-36, 38-43, 45-46, 81-88, 92-98 are rejected under 35 U.S.C. 112,

second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention.

17.   Claims 1, 2, 10-12, 16, 35-36, 38-43, 46, 81-88, 92-94, 97-98 (claims 3-9, 13, 17-33, 95-

96 dependent thereon) are indefinite in the recitation of "sequence encoding a coding and/or non-

coding sequence", "coding and/or non-coding amino acid sequence", "comprises the amino acid

sequence of .. and further comprises a coding and/or non-coding sequence" for the following

reasons. The term "coding and/or non-coding sequence" already refers to a nucleic acid

sequence. There is no coding/non-coding amino acid sequence as the term "coding" refers to the

coding of polynucleotides to proteins (only polynucleotides will encode proteins). As known in

the art, not all polynucleotides will encode a protein. Therefore, the terms "sequence encoding a

coding and/or non-coding sequence" and "coding and/or non-coding amino acid sequence" are

unclear and confusing because a nucleotide sequence cannot encode another nucleotide sequence

and a protein does not have a coding/non-coding sequence. For examination purposes, it will be

assumed that the term "sequence encoding a coding and/or non-coding sequence" reads "a coding

and/or non-coding sequence". No patentable weight will be given to the term "coding and/or

non-coding amino acid sequence" or "comprises the amino acid sequence of .. and further

comprises a coding and/or non-coding sequence". Correction is required.

18.   Claims 1, 2, 10-12, 16, 35-36, 38-43, 45, 46, 81-88, 92-94, 97-98 (claims 3-9, 13, 17-33,

95-96 dependent thereon) are indefinite in the recitation of "lacking a homologous signal

sequence or comprising a heterologous signal sequence in place of the homologous signal

sequence", "lacking a nucleic acid encoding a homologous signal sequence or comprising a

nucleic acid encoding a heterologous signal sequence in place of the nucleic acid encoding the

homologous signal sequence", "lacking a nucleic acid encoding a homologous signal sequence or

comprising a nucleic acid sequence encoding a heterologous signal sequence in place of the

nucleic acid sequence encoding the homologous signal sequence", and similar language for the

following reasons. While it is clear that the intended polypeptides are ones which lack the

homologous signal sequence, and the intended polynucleotides are ones which encode

polypeptides lacking the homologous signal sequence, as written, the terms "comprising a

heterologous signal sequence in place of the homologous signal sequence" and "comprising a

nucleic acid encoding a heterologous signal sequence in place of the nucleic acid encoding the

homologous signal sequence" are unclear and confusing within the context of the claims in view

of the fact that these terms are associated with polypeptides/polynucleotides which have the

homologous signal sequences in place. For clarity, it is suggested that the claims be amended by

deleting the terms "comprising a heterologous signal sequence in place of the homologous signal

sequence" and "comprising a nucleic acid sequence encoding a heterologous signal sequence in

place of the nucleic acid sequence encoding the homologous signal sequence", and adding a new

item with the heterologous signal sequence limitation dependent upon the item which merely

lacks the homologous signal sequence. For example, claim 1 can be amended to recite "a

recombinant expression system.....a phytase enzyme (i) comprising the amino acid sequence

of..., (iii) comprising the amino acid sequence of SEQ ID NO: 2 but lacking a homologous

signal sequence, (iv) comprising the amino acid sequence of (iii) further comprising a

heterologous signal sequence....", (v) comprising the amino acid sequence of SEQ ID NO: 2

from amino acids 1-432 but lacking a homologous signal sequence, (vi) comprising the amino

acid sequence of (v) further comprising a heterologous signal sequence ......". Claim 2 can be

amended to recite, for example, "a vector comprising a nucleic acid (i) comprising the nucleotide

sequence of SEQ ID NO: 1...., (iii) comprising the nucleotide sequence of (i) or (ii) lacking a

nucleic acid sequence encoding a homologous signal sequence, (iv) comprising the nucleotide

sequence of (iii) further comprising a nucleic acid sequence encoding a heterologous signal

sequence.....". Correction is required.

19.   Claims 36, 38-43 are indefinite in the recitation of "comprising a nucleic acid (i).....(viii)

comprises the amino acid sequence..." for the following reasons. While the preamble indicates

that items (i)-(ix) are in reference to a nucleic acid, item (viii) refers to protein since only a

protein can have an amino acid sequence. For examination purposes, item (viii) will be

interpreted as reading "encodes a polypeptide comprising the amino acid sequence ....".

Correction is required.

20.   While the Examiner has attempted to carefully review all the pending claims for proper

antecedent basis, clarity, consistency, spelling, and grammar, in view of the large number of

claims and the substantial amount of text in each of these claims, Applicant is requested to

carefully review the claims prior submission of amendments for proper antecedent basis, clarity,

consistency, grammar and spelling.

Claim Rejections - 35 USC § 112, First Paragraph

21.   The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

22.   Claims 11, 12, 13, 29, 36 remain rejected under 35 U.S.C. 112, first paragraph, because

the specification, while being enabling for an isolated host cell comprising the polynucleotide of

SEQ ID NO: 1, does not reasonably provide enablement for non-isolated host cells comprising

the polynucleotide of SEQ ID NO: 1 or variants thereof encompassed by the claims. The

specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention commensurate in scope with these

claims.

23.   This rejection has been discussed at length in the Non Final action of 6/30/2006.

24.   Applicant argues that the amendments made to the claims address this rejection.

25.   While it is agreed that the amendments made address some of the issues regarding this

rejection, it is noted that the instant claims still require non-isolated cells. Thus, for the reasons

extensively discussed in the prior Office action with regard to non-isolated cells and how they

encompass cells within a transgenic animal, this rejection is <u>maintained</u>.

Claim Rejections - 35 USC § 102

26.   The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

27.   Claims 10-13, 24-33 were rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Van Ooijen et al. (U.S. Patent No. 5593963, issued on 1/14/1997, filed on 11/2/1993; cited in the IDS).

28.   In view of Applicant's amendment and the fact that the claims no longer recite nucleic acids encoding phytases which comprise fragments of the polypeptide of SEQ ID NO: 2, this rejection is hereby withdrawn.

Conclusion

29.   No claim is in condition for allowance.

30.   Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31.   Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

32.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts

to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
December 8, 2006